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**Toshiba America Medical Systems, Inc.**  
**Pre-Market Notification 510(k) for INFX-8000C**

**510(k) Summary**

**Date:** June 3, 2008 **JUN 23 2008**

**Submitter's Name:** Toshiba America Medical Systems, Inc.

**Submitter's Address:** P.O. Box 2068, 2441 Michelle Drive,  
Tustin, CA 92781-2068

**Submitter's Contact:** Paul Biggins, Director Regulatory Affairs  
(714)730-5000

**Establishment Registration Number:** 2020563

**Device Proprietary Name:** INFX-8000C (Infinix CCI and Infinix VCI)

**Common Name:** Electrostatic Fluoroscopic x-ray System)  
[Fed. Reg. No. 892.1650, Pro. Code: 90MQB]

**Regulatory Class:** II (per 21 CFR 892.1650)

**Performance Standard:** 21 CFR Subchapter J,  
Federal Diagnostic X-ray Equipment Standard

**Predicate Device(s):** GE Innova 4100; 510(k) Control # k052412  
Toshiba DFP-8000D/FPD; 510(k) Control # K052884

**Reason For Submission** Model Number Change

**Description of this Device:**

These systems are single or dual plane systems that employ x-rays to obtain fluoroscopy or radiography images of the body. The system is comprised of a computer system, support arms (that contain the tube and solid state detector), x-ray generator and a patient table.

**Summary of Intended Uses:**

This device is a digital x-ray system configured for use as a diagnostic x-ray angiography system. This x-ray angiography system is used for diagnostic and interventional procedures for cardiac blood vessels, cerebral blood vessels, abdominal blood vessels and lower extremities.

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**Technological Characteristics:**

This device employs similar materials and processes as found in the predicate device. The device produces ionizing radiation that is employed to generate fluoroscopic and radiographic images of the anatomy.

**Safety and Effectiveness Concerns:**

This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR § 1020, that apply to this device, will be met and reported via an initial report. Additionally this system is in conformance with the applicable parts of the IEC 60601-1 {applicable portions}; IEC 60601-2-32, and IEC 60601-2-28. - Medical Device Safety standards.

**Substantial Equivalence:**

The INFX-8000V is of comparable type and substantially equivalent to:

GE Innova 4100; 510(k) Control # k052412

Toshiba DFP-8000D/FPD; 510(k) Control # K052884

Therefore the INFX-8000V complies with the same or equivalent standards and has the same intended use as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 23 2008

Toshiba America Medical Systems, Inc.  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

Re: K081621

Trade/Device Name: INFX-8000C; Infinix-CCi and Infinix-VCi  
Regulation Number: 21 CFR 892.1650  
Regulation Name: Image-intensified fluoroscopic x-ray system  
Regulatory Class: II  
Product Code: MQB  
Dated: June 6, 2008  
Received: June 9, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

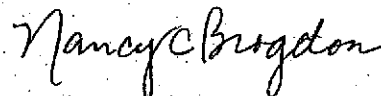
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

Toshiba America Medical Systems, Inc.  
Pre-Market Notification 510(k) for INFX-8000C

## Indications for Use

510(k) Number (if known):

K081621

Device Name: INFX-8000C; Infinix-CCi and Infinix- VCI

Indications for Use:

This device is a digital radiography/fluoroscopy system used in a diagnostic angiography configuration. This system is indicated for use in diagnostic and angiographic procedures for blood vessels in the heart, brain, abdomen and lower extremities.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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*Agne M. Whang*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, and  
Radiological Devices  
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